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Title: Quality Management System Audits		

1.0 PURPOSE:

This purpose of this document is to define the process by which the Program Management Office shall schedule, conduct, and report results of Quality Management System audits with the objective of identifying improvement opportunities, proactively mitigating risk and creating an environment of continual improvement.

2.0 RESPONSIBILITIES:

2.1 Quality Management – Quality Management shall:

- Ensure Quality auditors have been trained in accordance with the requirements of Table 1, this document
- Establish a quality audit schedule, taking into consideration past performance, which ensures Project Delivery functions and active projects receive an annual audit
- Ensure audits are conducted by personnel independent of the activity being audited
- Review audit findings and reports to ensure consistent reporting of Project Delivery activities

2.2 Auditors – It is the responsibility of auditors to conduct quality audits in accordance with the established audit schedule and the requirements of this document. Auditors shall be responsible for:

- Professional and objective conduct during audits
- Review of documentation applicable to the scope of the audit
- Preparation of checklists to facilitate a thorough evaluation of the audit scope
- Determine, based on the scope of the audit, affected process owners, auditees and stakeholders to invite to the opening and closing meetings
- Thoroughly describing and reviewing improvement opportunities and comments found during the audit to the auditees during the Closing Meeting
- Development and submission of the Final Audit Report to Quality Management for review and approval

2.3 Business Process Owners/Stakeholders/Auditees – This group shall be responsible to accommodate the auditors, make themselves available to participate in interviews, and provide objective evidence of compliance with procedures, plans and specified requirements. In addition, this group shall be responsible to be open and honest with auditors so as to help identify improvement opportunities to be addressed through corrective or preventive actions. Opportunities cannot be acted upon unless they are known.

3.0 SCOPE/APPLICABILITY:

All Project Delivery organizational functions, consultants and its contractors shall comply with the requirements of this document and be subject to audits for compliance with established procedures, plans, and specified requirements.

4.0 REFERENCES:

- [QM-10 Corrective and Preventive Action Procedure](#)

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5.0 DEFINITIONS & ACRONYMS:

- 5.1 **Audit:** A planned and documented investigative evaluation of a document, activity or process to establish continual improvement opportunities by determining the adequacy, effectiveness and compliance with established standards, policies, procedures, or specified requirements.
- 5.2 **Audit Finding:** Any error, exception or deficiency noted as a result of an examination of evidence collected during an audit. Findings generally relate to (a) compliance with specified requirements, (b) adequacy and effectiveness of process controls and/or (c) efficiency and effectiveness of administrative or management activities.
 - 5.2.1 **Audit Finding Classifications -**
 - Corrective: A noted opportunity where action is required to eliminate the recurrence of root causes of deficiencies and/or ineffective controls from specified requirements
 - Preventive: A noted opportunity where action is required to eliminate the causes of potential deficiencies from specified requirements and/or risks not yet addressed
 - Correction: A single mistake, incident or deficiency from specified requirements where correction may be needed, but no requirement for "root cause" investigation is necessary
- 5.3 **Corrective Action:** Actions taken to correct and eliminate recurrence of root causes for deficiencies and/or ineffective controls from specified requirements
- 5.4 **Preventive Action:** Actions taken to eliminate the causes of potential deficiencies from specified requirements and/or risks not yet addressed
- 5.5 **Continual Improvement:** The combination of all actions taken to improve the adequacy and effectiveness of an organizations ability to satisfy both internal and external customers, either documented or implied
- 5.6 **Lead Auditor:** An individual who meets the minimum requirements of Table 1 of this document and is assigned the additional responsibility to lead a team of auditors in the performance of an audit
- 5.7 **Auditor:** An individual who meets the minimum requirements of Table 1 of this document
- 5.8 **Auditee:** A person or organization that is being audited
- 5.9 **Stakeholders:** An individual, group or organization whose impact on or actions are affected by the process outcome and/or deliverable
- 5.10 **Auditor Comments:** Notes documented by an auditor to highlight commendable efforts and/or to provide an awareness to auditees of areas for possible improvement, but do not require formal action

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6.0 PROCEDURE:

6.1 Selection of Auditors

- 6.1.1 Quality Management shall select auditors to fulfill the audit schedule in accordance with the requirements of Table 1
- 6.1.2 Auditors selected shall be independent of the activity being audited

Type of Training	Frequency	Objective Evidence
Auditor Certification	Once ^(1,2)	Certified Quality Auditor certificate from a recognized professional agency
Lead Auditor Training	Once ^(1,2)	Lead Auditor training certificate from a recognized professional agency
Auditor Training Class	Once ^(1,2)	Attendance of an NTTA sponsored Audit Training Class
Auditor Evaluation	Annually ⁽³⁾	Quality Management shall randomly select a minimum of three completed auditor reports, witness at least one audit and evaluate the auditor's performance. This evaluation shall be recorded on form QM-08-F4.
NOTE 1: Only one type of training is required		
NOTE 2: Approved by Quality Management		
NOTE 3: Indicates calendar year		
Table 1		

6.2 Audit Schedule

- 6.2.1 Quality Management shall publish and approve an annual audit schedule and make it available to staff
- 6.2.2 The audit schedule shall take into consideration current conditions, importance of the business function/process and previous corrective/preventive action activity within Project Delivery
- 6.2.3 Quality Management, at their discretion, may either increase or decrease the amount of audits performed in a particular area based on performance or activity levels ensuring areas of risk are prioritized and adequately addressed

6.3 Audit Preparation

- 6.3.1 Quality Management shall generate and submit to the Director of Project Delivery an executive communication describing audit objectives, scope and time frame in advance of conducting the audit
- 6.3.2 Auditors shall review documentation applicable to the audit scope to familiarize themselves with the specified requirements
- 6.3.3 Auditors shall review the previous audit report of similar scope to determine areas of follow-up, inclusive of resulting corrective or preventive improvement actions
- 6.3.4 Auditors shall supplement the standard checklist, form QM-08-F1, by adding scope specific questions after reviewing the specified requirements and previous audit results of similar scope
- 6.3.5 Auditors shall determine, based on the scope of the audit, affected process owners, auditees and stakeholders to invite to the opening meeting
- 6.3.6 Auditors shall schedule an opening meeting in advance of the start of the audit

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6.4 Opening Meeting

- 6.4.1 Auditors shall conduct the opening meeting to establish:
- The scope and duration of the audit
 - Final Audit Report date
 - The identification of auditee points of contact and availability for the audit
 - Handling of audit findings/opportunities
 - The approximate date of the Closing Meeting
 - The content of the Final Audit Report

6.5 Conducting Audits

Quality Management System audits shall be conducted in a professional and courteous manner. As it is the objective of the audit program to identify improvement opportunities and proactively mitigate risk, the professional manner in which the audit is conducted serves to communicate this intent and to facilitate an environment of continual improvement.

- 6.5.1 Auditors shall conduct audits using prepared audit checklists, but shall not be limited to those questions on the checklists. Auditors shall be free to follow the audit trail to accurately and thoroughly assess intent and compliance to specified requirements
- 6.5.2 Auditors shall maintain their completed checklist (QM-08-F1), supporting documentation and comments made during the audit to support audit conclusions
- 6.5.3 Auditors shall maintain a list of those individuals interviewed (QM-08-F2) during the audit by name and role to support the audit record
- 6.5.4 At the conclusion of the audit, the auditor shall review all potential improvement opportunities with the auditees to ensure audit findings/comments are understood and reflect actual observed conditions. The auditee shall be afforded a maximum of 24 hours to provide auditors with (additional) objective evidence that would prevent a potential audit finding.

6.6 Closing Meeting

- 6.6.1 Auditors shall conduct a Closing Meeting inviting the affected process owners and those expected to take ownership of improvement actions. This meeting may also include invitees from the Opening Meeting. During the Closing Meeting the auditors shall communicate:
- Review of the scope of the audit
 - Areas of commendable efforts and/or contributions exceeding expectations (good points)
 - Review of Audit findings and comments
 - Identification and ownership of improvement actions, inclusive of expected response times
 - Handling of audit findings/opportunities
 - The expected date and distribution of the Final Audit Report

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6.7 Final Audit Report

6.7.1 Audit reports shall be reviewed and approved by Quality Management prior to issuance to the Director of Project Delivery and distribution to affected process owners and stakeholders. The report shall be issued within 10 working days of the Closing Meeting. The final audit report shall be formatted using form QM-08-F3 and contain the following minimum information:

- Audit number
- Audit date
- Audit scope and objectives
- Affected Process Owners
- List of those interviewed (auditees)
- Final Audit Report distribution
- Executive Summary
- Commendable efforts and/or contributions exceeding expectations (good points)
- Description of audit findings, inclusive of CAR/PAR numbers with identified ownership

6.8 Issuance of Improvement Opportunities

6.8.1 Following the issuance of the Final Audit Report, auditors shall issue improvement opportunities in the form of Corrective or Preventive Action Requests (CARs & PARs) in accordance with document *QM-10, Corrective and Preventive Action Procedure*

6.8.2 CARs/PARs shall be issued to the identified improvement action owners

6.8.3 All CARs/PARs shall be issued within 5 days of issuance of the Final Audit Report. Recipients shall respond to CARs/PARs in accordance with the requirements of document *QM-10, Corrective and Preventive Action Procedure*.

6.9 Audit Follow-up

6.9.1 Audit follow-up shall not be considered part of this procedure as this activity is handled as part of the verification and validation activities identified in document *QM-10, Corrective and Preventive Action Procedure*.

6.10 Audit Records

6.10.1 The audit record shall be the responsibility of the auditor, consist of the following items and be filed electronically in the NTTA approved repository:

- Completed audit checklist (QM-08-F1)
- Auditee listing (QM-08-F2)
- Audit Final Report (QM-08-F3) with the objective evidence supporting audit conclusions
- Executive communication to the Director of Project Delivery
- Communication providing evidence of Final Report distribution

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6.11 Audit Number Format

6.11.1 All Quality Management System audit numbers shall conform to the following format:

- QMS-XXXXXX
 - Where QMS represents "Quality Management System"
 - Where XXX represents the three letter initials of the lead auditor
 - Where YYYY represents a sequential number starting at 0001 (for each auditor)

6.12 Audit Metrics

6.12.1 The following metrics shall be maintained and updated quarterly by the Quality Department providing management with operational performance, improvement opportunity achievements and measures of customer satisfaction of the audit program:

- Number of improvement opportunities identified (corrective and preventive actions issued)
- Number of improvement opportunities identified by Project Delivery Business Function
- Number of audits planned verses audits performed
- Percentage of audit reports issued within 10 days of the Closing Meeting
- Percentage of improvement opportunities issued within 5 days of the Final Report
- Results of Audit surveys providing a measure of customer satisfaction (completed by auditees)

7.0 REGULATORY REQUIREMENTS:

N/A

8.0 RELATED BOARD POLICY:

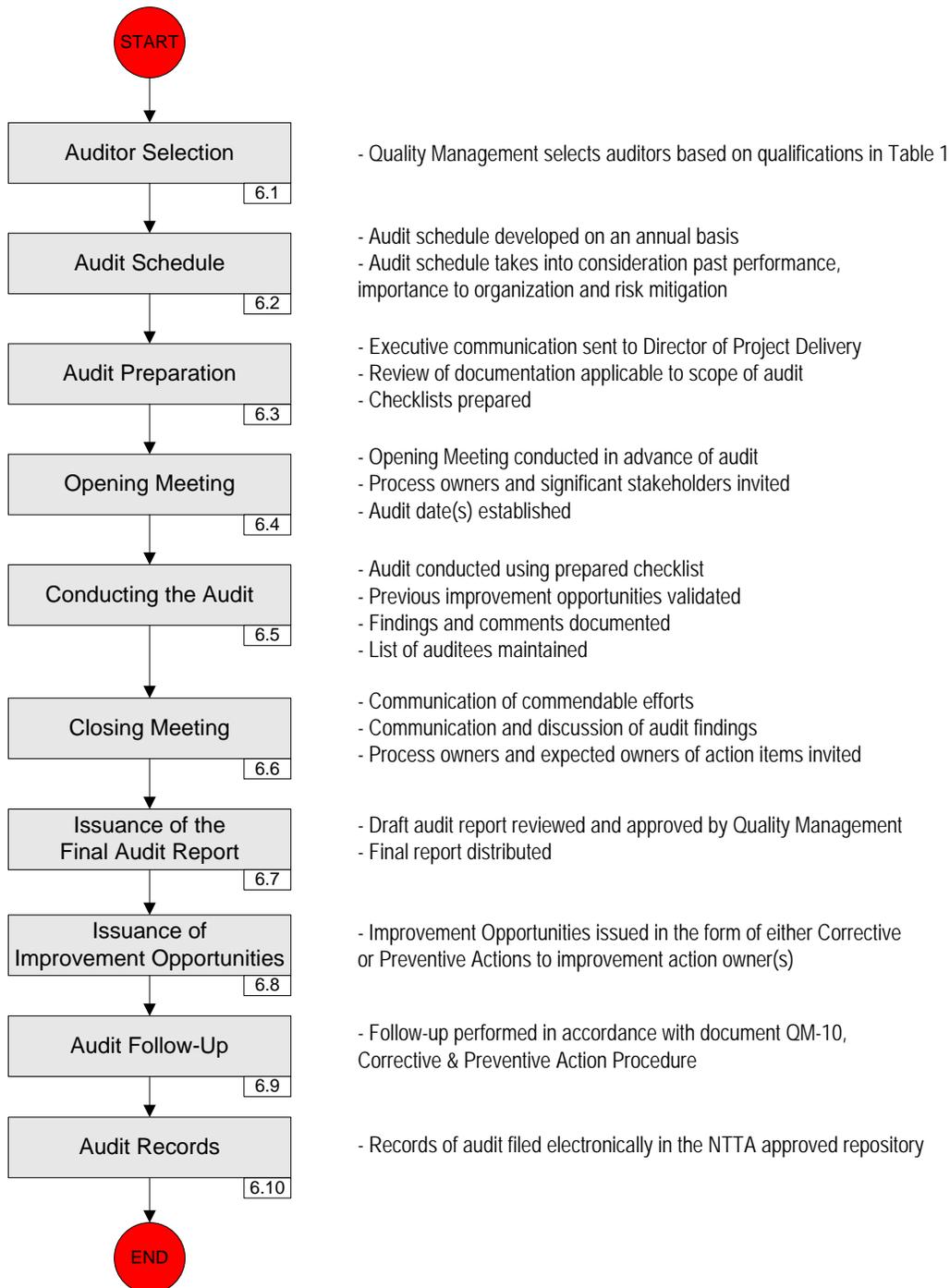
N/A

9.0 COMPONENT DOCUMENTS:

- [Audit Checklist \(QM-08-F1\)](#)
- [Auditee Listing \(QM-08-F2\)](#)
- [Final Audit Report \(QM-08-F3\)](#)
- [Auditor Evaluation \(QM-08-F4\)](#)
- [Audit Schedule \(QM-08-A1\)](#)

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10.0 FLOWCHART



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11.0 REVISION HISTORY:

Revision	Revised by:	Date Issued	DRN	Reason for Revision
0	Micki Ellis	06/05/2008		Original Issue
1	Troy Federspiel	05/11/2009	10002	Global changes to the procedure
2	Peter Claypool	01/26/2010	10093	Major rewrite of procedure with additional forms created <ul style="list-style-type: none"> • Abbreviated purpose identifying audit objectives • Revised responsibilities to reflect current practice • Added definitions • Removed Major/Minor finding classifications in paragraph 5.0 and redefined • Flipped paragraphs 6.1 and 6.2 for clarification • Added paragraph 6.3, auditor preparation • Added paragraphs 6.6.4 & 6.6, Opening/Closing Mtg • Added paragraph 6.7, Final Audit Report • Added paragraph 6.6, Audit follow-up • Added paragraph 6.10, Audit records • Added paragraph 6.11, Audit number format • Added paragraph 6.12, Audit Metric • Revised flowchart to reflect current workflow • Added forms: <ul style="list-style-type: none"> • QM-08-F1, Audit Checklist • QM-08-F2, Auditee Listing • QM-08-F3, Audit Final Report template • QM-08-F4, Auditor Evaluation • QM-08-A1, Audit Schedule